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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,247	07/13/2001	Yi-Bao Ke	04399/000j615-US0	4883
7590	12/16/2004		EXAMINER	
DARBY & DARBY P.C. 27th Flr. 805 Third Avenue New York, NY 10022			DESAI, ANAND U	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/905,247

**Applicant(s)**

KE ET AL.

**Examiner**

Anand U Desai, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 12-15 and 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I, drawn to claims 1-11, and 16 in the reply filed on October 20, 2004 is acknowledged. The traversal is on the ground(s) that the pending claims are all drawn to a single inventive concept and as such should be examined in a single application. This is not found persuasive because as discussed in the requirement for restriction, the claims are drawn to five distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 12-15, and 17-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 20, 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Priority***

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. The priority date is August 2, 2000.

### ***Information Disclosure Statement***

4. The information disclosure statement (IDS) submitted on September 26, 2001, October 22, 2001, and July 18, 2002 are being considered by the examiner.

*Specification*

5. The disclosure is objected to because of the following informalities:
6. The abstract of the disclosure is objected to because of the word, “etc” in the 3<sup>rd</sup> sentence. Suggest removing the word or describing particular treatments. Correction is required. See MPEP § 608.01(b).
7. A specific priority reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. Suggest, “This application claims priority under 35 U.S.C. 119(a)-(d) to Chinese applications, 00119553.0, filed August 2, 2000, and 001103102.6, filed January 18, 2001.”
8. On page 3, lines 6-8, the sentence about dysfunctional immune response is unclear. What is “remains strong positive” describing?
9. On page 5, line 25, what is the word, “etc” describing? Suggest describing biological activities or removing the word.
10. On page 12, line 12, what is the word, “etc” describing? Suggest describing the standard methods or removing the word.
11. On page 15, lines 11-14, the sentence is unclear? Does the deletion have no effect on its RIP activity?
12. On page 15, line 16, there appears to be a typographical error, the word, “inventers” appears to be intended to be “inventors.”

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-11, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15. In claim 1, it is not clear what the mutant trichosanthin protein amino acid sequence encompasses, since the native trichosanthin protein does not have a reference sequence disclosed. Suggest, identifying the native trichosanthin sequence as SEQ ID NO: 1.

16. The term "low" in claim 1 is a relative term, which renders the claim indefinite. The term "antigenicity" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. What are the criteria for low antigenicity?

17. The term "substantially" in claim 1 is a relative term, which renders the claim indefinite. The phrase "retaining the biological activities" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. What function of trichosanthin is considered to substantially retain biological activity for the protein?

18. In claim 1, it is not clear what the metes and bounds of "biological activities" would be encompassed by the mutant trichosanthin?

19. In claim 1, what is meant by modification?

20. In claim 2, insertion and addition in the Markush group appears redundant?

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21. In claim 9, it is not clear what is meant by modified?
22. Claims 3-8, 10, 11, and 16 are rejected for depending on a rejected claim.

23. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

24. Claims 1-11, and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a fragment or derivative thereof of a mutant trichosanthin polypeptide. To satisfy the written description requirement, the specification must describe the invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. The specification does not describe the structure, that is amino acids in the various polypeptides that can be altered without affecting the function of a specific polypeptide. For one to be in possession of the claimed invention, the inventor would have to know the functional consequences of structural alterations. Thus due to the limited predictability in the art, a skilled artisan would not find adequate support for fragment and derivatives thereof of a mutant trichosanthin polypeptide as disclosed in the claims in the specification.

***Claim Rejections - 35 USC § 102***

25. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

26. Claims 1-4, 8, 9, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee-Huang et al. U.S. Patent 5,532,214. Lee-Huang et al. disclose a protein obtainable from the root tuber of a plant of the genus *Trichosanthes* that includes the amino acid sequence identified as SEQ ID NO:1 (see U.S. Patent '214, column 27, claim 1 and SEQ ID NO:1). Lee-Huang et al. also discloses the use of protein sequence to treat HIV infection (see U.S. Patent '214, abstract, current application, claim 16). The sequence contains the amino acid sequence of native trichosanthin that has been modified, wherein the modification is deletion of carboxy terminal amino acids of the currently claimed mutant trichosanthin. SEQ ID NO:1 also contains modifications compared to the currently claimed fragment or derivative of mutant trichosanthin, wherein the modification is a replacement of the amino acid Ser with Lys (see position 35 and 36 of currently claimed mutant trichosanthin with position 12 and 13 of SEQ ID NO:1, current application, claim 3). SEQ ID NO:1 of U.S. Patent '214 has 80 % local similarity with amino acids 24-68 of the currently claimed mutant trichosanthin (current application, claims 1-4, 8, and 9).

27. Claims 1-4, 6, 7, 9, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Siegall U.S. Patent 5,541,110. Siegall discloses a ribosome-inactivating protein, bryodin 1. The

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ribosome-inactivating protein is one of the same biological activities of the native trichosanthin. The ribosome-inactivating protein is identified as SEQ ID NO:2 in U.S. Patent '110. SEQ ID NO:2 has 60% identity with trichosanthin, and is therefore interpreted as a derivative of currently claimed mutant trichosanthin. SEQ ID NO: 2 has a Asparagine to Glycine replacement at amino acid position 220 (see U.S. Patent '110, SEQ ID NO:2, position 243, current application, claim 6), and a Threonine to Glycine replacement at amino acid position 204 (see U.S. Patent '110, SEQ ID NO:2, position 227, current application, claim 7). SEQ ID NO:2 has modifications within amino acid regions 174 to 180 (see U.S. Patent '110, SEQ ID NO:2, amino acids 196 to 202, particularly Aspartic acid at position 176 (current application nomenclature) is modified to a Tyrosine amino acid), and amino acid regions 203 to 226 (see above current application, claim 6 and 7 explanation), therefore the protein is a derivative modified in each of one of any two of said three regions according to-claim 1 (current application, claims 1-4, and 9). Siegall also discloses the use of composition comprising the ribosome-inactivating protein to selectively kill undesired cells such as cancer cells (see U.S. Patent '110, abstract, current application, claim 16).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

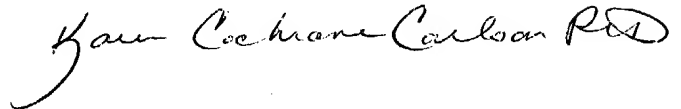
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 7, 2004

A handwritten signature in cursive script, likely belonging to a patent examiner or official.A handwritten signature in cursive script that reads "Karen Cochrane Carlson PhD".

KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER